# BIOSAFE Anemia $Sure^{TM}$

Rapid Anemia Test

Disease Category:

Anemia

Disease State:

Chronic Kidney Disease, HIV, Oncology, Diabetes, Anemia

Product:

BIOSAFE AnemiaSure™ Rapid Anemia Test

### **Product Description:**

Low cost, single use, disposable unit is for consumer and professional use. Designed and developed by BIOSAFE's research and development team to measure hemoglobin levels and provide a simple yes/no answer to the question, "Am I anemic, this FDA approved and CLIA waived device provides a result in 20 minutes that is both easy to understand and as accurate as a standard laboratory analysis. The product is available free of charge to chronic kidney disease, HIV, oncology and diabetes patients though AMCEN in the product is a standard laboratory disease.

disease, HIV, oncology and diabetes patients though AMGEN in support of Epogen® and Aranesp®.

# Competitive Advantages:

The BIOSAFE AnemiaSure<sup>TM</sup> Rapid Anemia Test:

- FDA approved; CLIA waived
- No equipment to buy
- Results in 20 minutes
- Single-Use, Rapid Response Anemia Device
- As accurate as a laboratory test
- A quick and convenient way for physicians to test patients in the office

# **BIOSAFE HEMO-QUANT**

Rapid Anemia Test

Disease Category:

Anemia

Disease State:

Chronic Kidney Disease, HIV, Blood Disorders, Diabetes, Anemia

Product:

BIOSAFE Hemo-Quant Rapid Anemia Test

#### **Product Description:**

Low cost, single use, disposable unit is for professional use by physicians and hospitals. Designed and developed by BIOSAFE's research and development team to measure hemoglobin levels, this FDA approved and CLIA waived device provides a result in less than 10 minutes that is both easy to understand and as accurate as a standard laboratory analysis. The product will be available through major medical products' distributors and will be priced to support third-party reimbursement.

#### **Professional Markets:**

- Primary Care Physicians
- Hospitals
- Critical Care
- Dialysis Providers
- Diabetes Management
- **Blood Banks**
- Dialysis Care

#### Competitive Advantages:

The BIOSAFE Hemo-Quant Rapid Anemia Test:

- FDA approved; CLIA waived
- No equipment to buy
- Results in 10 minutes
- Single-Use, Rapid Response Anemia Device
- As accurate as a laboratory test
- A quick and convenient way for physicians to test patients in the office

### **BIOSAFE A1c (DIABETES)**

Disease Category:

Diabetes - Diagnosis and Disease Management

Disease State:

Diabetes

Product:

BIOSAFE A1c Test (Diabetes) a.k.a. BIOSAFE Diabetes Test

#### **Product Description:**

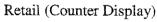
The micro sample blood test is a self-contained collection kit approved for patient self-collection or professional use. The consumer or physician collects 3 drops of blood from the patient and mails the blood sample to BIOSAFE's laboratory for analysis. BIOSAFE Laboratories produces a consumer friendly report. The user



receives quantitative results from the test. No longer will it be necessary to go to a doctor's office or a laboratory to draw blood and then wait a period of time for the results. From a few drops of blood obtained from a finger nick, a quantitative A1c determination, with clinical accuracy, is obtained. The BIOSAFE A1c Test is appropriate for all consumers who have diabetes and wish to appropriately monitor and manage the disease. The test instructions direct the user to take the results from the test to his or her physician for consultation. This test is appropriate for physician use.

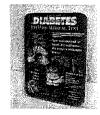
#### Packaging:

Pediatric Promotion Featuring "Doc Furby"



ter Display)

BIOSAFE Blood
Collection Card







#### Markets:

- Large Pharma in support of marketing and drug persistency programs
- Disease Management in support of diabetes management programs
- Retail Drug Retail Product; Customer health programs
- Clinical Trial & Research

#### Selected Customers by Category:

- Disease Management & Pharmacy Benefit Managers: Caremark, Matria, CCS, Focused Healthcare Solutions, CorSolutions, Shipps
- Retail Drug: Albertsons, Safeway, Osco, Kroger (Ralph's)
- Clinical Trial & Research: University of Michigan, Research Triangle Institute, Stanford University

# BIOSAFE RAPID LIVER FUNCTION TEST (ALT)

Disease Category: Li

Liver Dysfunction

Disease State:

Liver Disease, Liver Disease resulting from HIV, Oncology, Diabetes, Coronary Heart

Disease, Drug side effects on the Liver.

Product:

BIOSAFE Rapid Liver Function Test

a.k.a. BIOSAFE Instant ALT

#### **Product Description:**

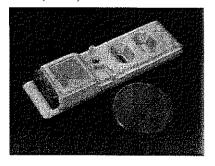
Low cost, single use, disposable unit is for consumer and professional use. Designed and developed by BIOSAFE's research and development team to measure ALT levels in the blood, this to be FDA approved and CLIA waived device provides a result in less than 10 minutes that is both easy to understand and as accurate as a standard laboratory analysis. The consumer friendly design of this product makes it especially easy to use for the first time user.

So many drugs have the potential for causing liver damage including the widely prescribed cholesterol reducing drugs from the class called "statins". These drugs include but are not limited to Lipitor<sup>®</sup>, Mevacor<sup>®</sup>, Zocor<sup>®</sup>, Pavacol<sup>®</sup>, and Crestor<sup>®</sup>. Approximately 13 million people take statins and should have their liver checked regularly.

#### Is my Liver Healthy? - How do you know?

The BIOSAFE rapid ALT test provides a general screening for liver dysfunction. A physician or consumer will use this product to monitor liver health. This is a low cost tool which will help keep the physician informed as to the patient's liver health.

#### **BIOSAFE Rapid Liver Function Test (ALT)**



#### Markets:

- Large Pharma in support of marketing and drug persistency programs
- Retail Drug Retail Product; Customer screening programs
- Web-based Retail on-line retail drug stores
- Foreign Market as an instant test, no local lab is required
- Clinical Trial & Research

#### Selected Potential Customers:

- Retail Drug: CVS, Walgreens, Albertsons, Safeway
- Web-based Retail: Amazon. Drugstore.com
- Medical Supply & Wholesale Distributors: McKesson, Cardinal
- Foreign Markets: Greece (VI Pharma); Italy

# BIOSAFE RAPID PROSTATE TEST (PSA NOW)

Disease Category:

Men's Health - Diagnosis and Disease Management

Disease State:

Prostate Disease

Product:

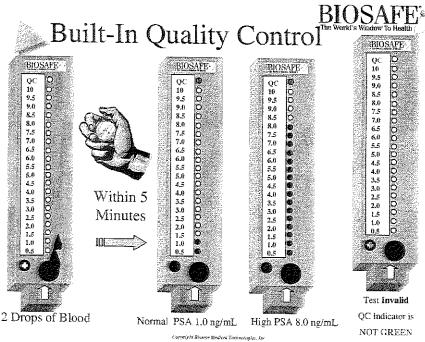
BIOSAFE RAPID PROSTATE TEST

a.k.a. BIOSAFE PSA NOW

#### **Product Description:**

Products in this series have been and will be selected based upon four criteria: (1) Physician need and desire for the product: (2) Consumer desire and understanding of the product; (3) Adequate market size and (3) BIOSAFE's ability to produce the product at a cost significantly below that currently being reimbursed by insurance companies. The PSA Device is being developed as a hand-held, consumer friendly, point-of-care device that will immediately give the user quantitative results of the test. This eliminates the need to go to a doctor's office or a laboratory to draw blood and then wait a period of time for the results.

From a few drops of blood obtained from a finger nick, the quantitative PSA Device will immediately determine, with clinical accuracy, the PSA level in the patient's or consumer's blood. Markets for the PSA Device will include: (1) routine clinical testing in the physician's office, (2) physician monitoring of effectiveness of treatment and monitoring of disease progression, (3) screening for large pharmaceutical companies to find customers for their drugs which treat prostate disease, including both prostate cancer and benign prostate hyperplasia, and (4) like the home pregnancy test, the PSA Device will be produced as an inexpensive retail product directed at men who suffer the symptoms of prostate disease, including difficulty in urination, frequent or urgent need to urinate and painful urination. The PSA Device will initially be used in physician's offices to screen for prostate disease, including prostate cancer, and to monitor disease treatment and progression. In 1999, physicians ordered 10 million PSA tests in the U.S.



#### Markets:

- Large Pharma in support of marketing and drug persistency programs
- Disease Management in support of men's health programs
- Retail Drug Retail Product; Customer screening programs
- Clinical Trial & Research

#### BIOSAFE ALLERGY TEST

Rapid Allergy Screen

Disease Category:

General Allergies

Disease State:

Product:

Indoor Allergies, Outdoor Allergies, Allergic Asthma BIOSAFE Allergy Test - a general allergy Screen

a.k.a. BIOSAFE IgE Test

**Product Description:** 

Low cost, single use, disposable unit is for consumer and professional use. Designed and developed by BIOSAFE's research and development team to measure IgE levels, this FDA approved and CLIA waived device provides a result in less than 10 minutes that is both easy to understand and as accurate as a standard laboratory analysis. The consumer friendly design of this product makes it especially easy to use for the first time user.

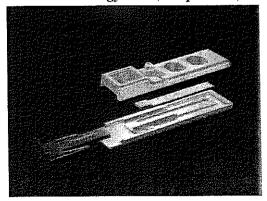
The product will be available through major medical products' distributors and will be priced to support thirdparty reimbursement. The BIOSAFE Allergy Test will be available through retail drug and internet-based retailers.

#### **Product Design**

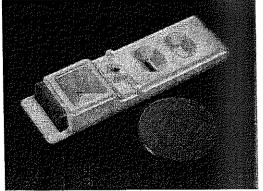
#### Allergy or Cold - How do you know?

The BIOSAFE rapid allergy test called the BIOSAFE Allergy Test begins with a general screening for allergies. A physician or consumer will use this product to determine the type of treatment required - Allergy or Cold. This is a low cost tool which will help the physician and consumers treat allergies and colds/flu with appropriate antibiotics or allergy treatments.

#### BIOSAFE Allergy Test (components)



# BIOSAFE Allergy Test (Assembled)



#### Markets

- Large Pharma
- Retail Drug
- Clinical Trial and Research

#### **BIOSAFE ALLERGY PANEL**

Rapid Allergy Panel

Disease Category:

General Allergies

Disease State:

Indoor Allergies, Outdoor Allergies, Allergic Asthma

Product:

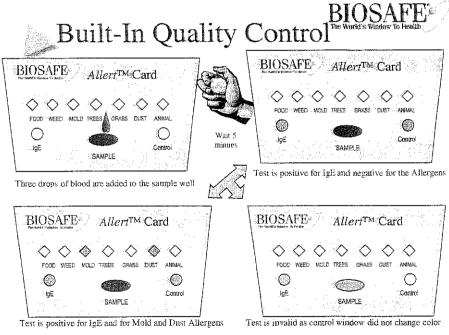
BIOSAFE Allergy Panel - a category specific allergy screen

#### **Product Description:**

Low cost, single use, disposable unit is for consumer and professional use. Designed and developed by BIOSAFE's research and development team to measure specific IgE levels by category, this FDA approved and CLIA waived device is a follow-up product to the BIOSAFE Allergy Test. This product can be custom designed to provide results in up to 7 categories. The BIOSAFE Allergy Panel provides results in less than 10 minutes that is both easy to understand and as accurate as a standard laboratory analysis. The consumer friendly design of this product makes it especially easy to use for the first time user.

The product will be available through major medical products' distributors and will be priced to support third-party reimbursement. The BIOSAFE Allergy Test will be available through retail drug and internet-based retailers.

#### Product Design



Copyright Biosoft Medical Technologies, inc

#### BIOSAFE ALLERGY REFLEX PANEL

Rapid Allergy Reflex Panel

Disease Category:

Specific Allergies by Category

Disease State:

Indoor Allergies, Outdoor Allergies, Allergic Asthma

Product:

BIOSAFE Allergy Reflex Panel

a specific allergy screen by category

#### **Product Description:**

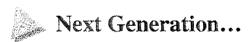
Low cost, single use, disposable unit is for consumer and professional use. Designed and developed by BIOSAFE's research and development team to measure specific IgE levels by category within an allergy group, this FDA approved and CLIA waived device is a follow-up product to the BIOSAFE Allergy Panel. A specific card is used for each category: Grass, Trees, Indoor Allergies, Outdoor Allergies, etc. This product can be custom designed to provide results in up to 7 categories. The BIOSAFE Allergy Reflex Panel provides results in less than 10 minutes that is both easy to understand and as accurate as a standard laboratory analysis. The consumer friendly design of this product makes it especially easy to use for the first time user.

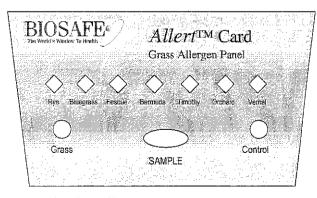
The product will be available through major medical products' distributors and will be priced to support third-party reimbursement. The BIOSAFE Allergy Test will be available through retail drug and internet-based retailers.

#### **Product Design**

To be used as a follow-up test to the BIOSAFE Allergy Panel:







BIOSAFE Allert<sup>TM</sup> Reflexive Panel Testing

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#### BIOSAFE C-REACTIVE PROTEIN

Disease Category:

Inflammation – Diagnosis and Disease Management

Disease State:

Infection, Arthritis, Inflammatory Disease

Product:

**BIOSAFE C-Reactive Protein** 

a.k.a. BIOSAFE C-RP

#### **Product Description:**

The micro sample blood test is a self-contained collection kit approved for patient self-collection or professional use. The consumer or physician collects 1-3 drops of blood from the patient and mails the blood sample to BIOSAFE's laboratory for analysis. BIOSAFE Laboratories produces a consumer friendly report. The user receives quantitative results from the test. No longer will it be necessary to go to a doctor's office or a laboratory to draw blood and then wait a period of time for the results. From a few drops of blood obtained from a finger nick, a quantitative C-RP determination, with clinical accuracy, is obtained. The test instructions direct the user to take the results from the test to his physician for consultation. This test is appropriate for physician use.

CRP is a general marker of infection and inflammation that alerts medical professionals that further testing and treatment may be necessary. CRP tests are not specific enough to diagnose a particular disease. The CRP test is also used to monitor patients after surgery or other invasive procedures to detect the presence of an infection during the recovery period. The test may be repeated to determine whether treatment of an inflammatory disease is effective since CRP levels drop as inflammation subsides.

Packaging:

Professional Use

Retail (Counter Display)

BIOSAFE Blood Collection Card

Image Not Available

Image Not Available



#### Markets:

- Disease Management in support of various disease management programs
- Retail Drug Retail Product; Customer health programs
- Clinical Trial & Research

#### Selected Customers by Category:

- Disease Management & Pharmacy Benefit Managers expected to use this product: Caremark, Matria, CCS, Focused Healthcare Solutions, CorSolutions, Shipps
- Retail Drug: To Be Announced
- · Clinical Trial & Research: University of Michigan, Research Triangle Institute, Stanford University

# BIOSAFE IgE MEDIATED ASTHMA PANEL

Disease Category:

Allergic Asthma, General Allergies

Disease State:

Indoor Allergies, Outdoor Allergies, Allergic Asthma

Product:

BIOSAFE IgE Mediated Asthma Panel

a category specific allergy screen plus total IgE

#### **Product Description:**

Designed and developed by BIOSAFE's research and development team to measure total IgE levels and 7 specific allergen levels in a patient's blood. BIOSAFE's Total IgE determination as well as the specific IgE determinations are based upon Pharmacia's ImmunoCAP technology, the world's gold standard for both Total and

Specific IgE testing\*. The BIOSAFE IgE Mediated Asthma Panel provides convenience access to IgE testing for the physician without the need for long term laboratory contracts, special equipment or staff. The BIOSAFE IgE Mediated Asthma Panel also is quick and easy for the patient. No special trip to a lab or venous blood draw is required

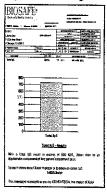
Genentech has adopted this kit as the standard for use by physicians in diagnosing IgE-Mediated Allergic Asthma and provides the kit to physicians free of charge to aid in both the diagnosing of IgE-Mediated Allergic Asthma and in dosing Xolair®.

# Packaging, Reporting and Proprietary Technology

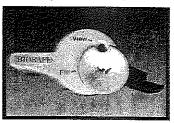
Physician Kit (as used by Genentech)



Physician Report



**BIOSAFE Blood Transport** System (BTS)



<sup>\*</sup> Williams PB, et al. Analytic precision and accuracy of commercial immunoassays for specific IgE: Establishing a standard J Allergy Clin Immunol June 2000; 105:1221-30.

## BIOSAFE LIVER PANEL

(GGT, AST & ALT)

Disease Category:

Liver Dysfunction

Case 1:07-cv-11135-JSR

Disease State:

Liver Disease, Liver Disease resulting from HIV, Oncology, Diabetes, Coronary Heart

Disease, Drug side effects on the Liver.

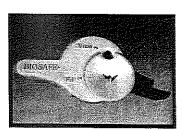
Product:

**BIOSAFE** Liver Panel

a.k.a. BIOSAFE GGT, AST & ALT

#### **Product Description:**

The micro sample blood test is a self-contained collection kit approved for patient self-collection or professional use. The consumer or physician collects 3 drops of blood from the patient and mails the blood sample to BIOSAFE's laboratory for analysis. BIOSAFE Laboratories produces a consumer friendly report. The user



receives quantitative results from the test. No longer will it be necessary to go to a doctor's office or a laboratory to draw blood and then wait a period of time for the results. From a few drops of blood obtained from a finger nick, a quantitative liver panel determination, with clinical accuracy, is obtained. The BIOSAFE Liver Panel is appropriate for consumers and patients who are taking statins to lower cholesterol values and who have a history of liver disease. The test instructions direct the user to take the results from the test to his physician for consultation.

So many drugs have the potential for causing liver damage including the widely prescribed cholesterol reducing drugs from the class called "statins". These drugs include but are not limited to Lipitor<sup>®</sup>, Mevacor<sup>®</sup>, Zocor<sup>®</sup>, Pavacol<sup>®</sup>, and Crestor<sup>®</sup>. Approximately 13 million people take statins and should have their liver checked regularly.

### Is my Liver Healthy? - How do I know?

The BIOSAFE Liver Panel provides a comprehensive screening for liver dysfunction. A physician or consumer will use this product to monitor liver health. This is a low cost tool which will help the physician remain informed as to the patient's liver health.

#### Markets:

- Large Pharma in support of marketing and drug persistency programs
- Retail Drug Retail Product; Customer screening programs
- Web-based Retail on-line retail drug stores
- Foreign Market as an instant test, no local lab is required
- Clinical Trial & Research

#### **Selected Potential Customers:**

- Retail Drug: CVS, Walgreens, Albertsons, Safeway
- Web-based Retail: Amazon. Drugstore.com
- Medical Supply & Wholesale Distributors: McKesson, Cardinal
- Foreign Markets: Greece (VI Pharma); Italy